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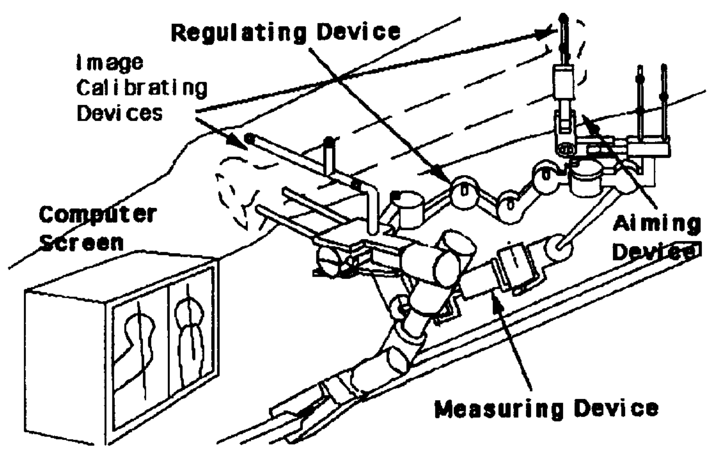
(54) **Title:** ORTHOPAEDIC SYSTEM ALLOWING ALIGNMENT OF BONES OR FRACTURE REDUCTION

(57) Abstract



- Schematic Representation of guiding wires in a particular position acting under Virtual Reality

The invention is relative to a system allowing to align either an instrument with a particular portion of the bone structure, or two bone segments between themselves during a fixation procedure, working under Virtual Reality conditions. In the first case, it can be used to introduce a screw, a Kirschner wire, or a drill in a body section of clinical interest, without trial drilling. In the second case, a fracture reduction and subsequent fixation can be operated eliminating doctor's X-rays exposure and greatly reducing also patient's. The system is composed by four main elements, the aiming device, provided with aiming bars, the image calibrating device (which can be coupled with the aiming device, used to determine initial angles and scales), a regulating device, connected to the fixator's clamps if a fracture reduction is required, or to the aiming device on one side and to the bone structure on the other (or to the operatory table, with a reduced precision), and a measuring device connected to a PC. This allows to present the actual alignment status in Virtual Reality on two planes once two calibration X-rays or fluoroscopies on approximately perpendicular planes have been performed and stored in the computer memory. Working principle of the system, coupling images with initially measured geometry, and the mathematical determination and visual display of the new position. The base of the aiming device is the fact that, if one aligns two planes with the body section of interest, introducing an instrument along the intersection of such planes will allow hitting the target. The aiming, coupled to the regulating device can also operate under fluoroscopy alone, needing in this case more radiation to reach the alignment. At the end of the alignment procedure, in the first case one can operate through the holes present on the aiming device, reaching the desired body portion, in the second case, one simply connects the end clamps with the desired fixator, or blocks the various degrees of freedom if the fixator carries its own regulating device.

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ORTHOPAEDIC SYSTEM ALLOWING ALIGNMENT OF BONES OR FRACTURE REDUCTION

Technical Field

During orthopaedic procedures it is often necessary to reach with a certain degree of precision a particular part of the bone structure either to fix internally a fracture, or to reach a tumour, or else to align fractured bones before placing an external fixator.

Background Art

Traditional surgery often operates by trial and error controlling under fluoroscopy the effect of the motion imposed. Sometimes, due to the impossibility of drilling holes knowing the drill position in a given frame of reference, most invasive surgery procedures are used, thereby requiring long periods of recovery for the patient. And, in any event, a massive dose of radiation is received by patient and doctors.

Disclosure of Invention

The present invention, coupling carefully chosen geometry, kinematic, measurement theory and computer science, provides a new generation of instruments allowing to position objects such as screws and bones, in the desired position, without any absorption of radiation by the doctor, and strongly reducing also the radiation to the patient, that has to receive only two fluoroscopies, used to calibrate the system.

This patent derives from two recent Italian patents applications, CS96A000011, presented on July the 25th 1996, and CS97A000004, presented on January the 27th 1997, and from the experience gained by the author during a surgical procedure to hit on the first attempt a osteoma-osteoide placed in the medial upper portion of the femur of a young lady. Basic instrument allowing the actual to virtual reality connection, the goniometer (measuring device) part of European Patent Application PCT/IT95/00225.

System Description

The complete system is composed by four elements, the aiming device, the image ca-

librating device, the regulating device and the measuring device coupled to a computer, also containing an image acquisition board, and specialised software.

The aiming device can be built in many different configurations, as described later, and could be used even only coupled to the regulating device, but in this case needs a greater usage of fluoroscopy.

Using the complete system, one can centre screws and similia into a particular portion of the body, working under Virtual Reality conditions. In fact, once the calibration images are acquired and repere point located, the computer will display on its screen in one plane at the time, or in two planes at the same time, the effect of the motion of the distal portion of the instrument with respect to the proximal portion, in the exact scale, thereby allowing the correct alignment, being the doctor helped also by a wise choice of the various degrees of freedom of the regulating device.

Vice versa, without the aiming device, the system can be used to align bones connected to clamps, in order to obtain a fracture reduction, once again working under Virtual Reality and acting on the clamps of a fixator. Also in this case the doctor will be able to observe the effect of its movements in the exact scale on the computer screen in one or two planes. A possibility of obtaining images also on a third plane is foreseen, and will be obtained via software. Let us now describe in greater details the various components.

Aiming Device

The aiming device is basically composed by an L shaped structure, whose angle between arms can be fixed or adjustable, being each arm of fixed or adjustable length, each arm bearing two bars lying on the same plane of the arm's hinge axis.

With reference to Figure 1, the simplest possible version of the aligner is made by a one piece element, bearing five holes whose axes are parallel, three aligned on a first plane, and the other two also aligned with one of the first three axes. Four aiming bars are inserted in four centring holes, while the fifth, aligned with each of the two remaining pairs, is left empty to serve as a guide for the instrument used to reach the region of clinical interest.

A more sophisticated version is depicted in Figure 2, where the angle and the bar's length are adjustable.

Sometimes the centring holes must be more than one, as in the case of fracture of the neck of a femur, where two screws have to be placed in a very little space.

Image Calibrating Device

The Image Calibrating Device is essentially made by two light structures that should carry a number of repere points (at least three per side and per image) used to mathematically determine, knowing their physical dimension, and their projection on the two calibrating images acquired by the computer, the picture scale and the angles determining the actual position of the measuring device.

Regulating Device

The Regulating Device is a mechanism allowing to adjust the position of the movable end (distal) of the instrument (i.e. the aiming device) or fixator, with respect to the fixed (proximal) end, by operating in sequence on independent planes. For this purpose it is composed by a series of hinges and telescopic kinematic pairs which have to be regulated in sequence in order to reach the required alignment. The regulating device may be part of the fixator's body, as in the case of US patent 5,152,280, may be part of the measuring device, or may be independent from both, but must allow independent regulation of the six degrees of freedom between end components working in sequence on independent planes.

Measuring Device

The Measuring Device is any device enabling to measure in real time the relative position between two bodies, passing the information directly to a computer. A possible execution of such a device can be the goniometer already quoted, but this is just an example.

Instrument Alignment Procedure

The alignment procedure under fluoroscopy requires the first two bars of the aiming

device to be aligned on the region of interest, so that the two bars are superimposed to the image of such region, being only one bar in sight. To do this, the doctor will have to act on the regulating device till the first alignment is reached. Next the system is blocked in such a way that it can only move within the first aiming plane. The X-ray apparatus is next rotated, and the second two bars are moved to align the region of clinical interest on the second direction. Blocking the device at this point will cause any instrument entering the guiding holes with a reduced tolerance to hit the region of interest.

If virtual reality operation is desired, the alignment on the first plane needs only to be approximate, but the image calibrating device is to be used. On the bars three spheres (or other aiming tool) of known position along the bars have to be located. The first X-ray is performed and the image (displaying the actual bar position with respect to the region of interest) supplied to the computer. Similarly one proceeds with a second X-ray on a plane approximately perpendicular to the first one, carrying also in this case the second pair of bars the minimum three aiming tools.

Once this is done, the computer will first calculate angles and scale on the base of the projections of the image calibrating device. Similarly to the fluoroscopic operation, the doctor will then move the distal portion of the instrument acting on the regulating device, observing the image as mathematically computed displayed on the computer screen. Once the first plane is centred, the doctor will block the system on a first plane, then proceed on the second plane adjustment. Only difference is that the image is now in Virtual Reality, but reproducing the actual geometry as calibrated by the computer.

Once also this alignment is reached, the introduction of an instrument through the centring hole will allow, placing the instrument/drill, where it is supposed to go. This time however there is also the possibility, if the geometry of all the tools involved is known, to compute also the penetration, so that the tip of the instrument will be brought to the appropriate depth.

Bone's Alignment procedure

If alignment of bones to be fixed with external fixator is desired, only the presence of

the aiming device is not required, everything else being needed.

To this end, either the fixator itself has a central body allowing to operate in sequence on its internal hinges or telescopes, working in sequence on perpendicular planes, as in the case of the fixator US patent 5,152,280, or a separate regulating device must be used. To this the image calibrating and measuring devices (and relative computer) are to be added, coupling them to the end clamps. The measuring device, such as the one described in IPN WO96/19944 of july 4th 1996, allows computing the effect of the motion performed by the doctor, showing in real time and with millimetric precision on the computer screen the new position of the bone segments in the proper scale.

Also in this case it is necessary to supply the computer two images in approximately perpendicular planes. Each image will show, the initial position of the bone segments, but also the position of the six point of known co-ordinates with respect to the measuring device clamps, belonging to the image calibrating device. Once identified their position, either automatically or manually (with the mouse) and acquired their position on the picture, the image calibration is automatically performed. Next the identification of the bones segments, again manual or automatic, follows. Figure 3 presents the system during alignment of instruments, while the following Figure 4 presents a fracture reduction. Figure 5 shows a possible configuration of one image calibrating device, of which four are needed (or two rateable), one per bone segment and per reduction plane (frontal and sagittal).

Should the fixator be not provided itself with the regulating device, this will have to be provided externally, being manual or electronically actuated.

Naturally this device may have a hinge sequence such as the quoted US patent, but may be totally different. In particular a configuration is here proposed in which the six degrees of freedom are supplied by three telescopic pairs (a, c, e) and three hinges (b, d, f), as shown in Figure 6. Naturally the end clamps have to be connected between the members designated in the Figure as member 1 and 2 respectively. Also notice that the relative position between the various constraints can be varied if necessary. Another possibility is presented in the following Figure 7. To further simplify the operator's work,

kinematic pair f can also be made as presented in Figure 8, so that e and f together will allow a pure translation and rotation about the diafisis. Naturally to do so the ring belonging to kinematic pair f must be centred in the diafisis and perpendicular to it. Small errors can however be corrected acting on the remaining constraints a, b, c and d. to obtain the correct position of f it is possible to utilise the instrument shown in Figure 9 guiding the insertion of the fixator's screws into the distal portion of the bone so that ring f be perpendicular to the diafisis.

The regulating device can also be coupled to the measuring device, as shown in Figure 9, where a, b, c, d, e, and f are designated as "measuring hinges", and where a possible "extensor device" is shown to be positioned between hinges a and b, in order to ease distraction of end clamps.

Last Figure shows a further scheme where the regulating/measuring device is motorised, being operated by simple switches.

As a final point, note that during fracture reduction it is not necessary to mount the regulating device before taking the calibration X-rays, but it is enough if the measuring and image calibrating devices are present. The regulating device can be installed only after the X-rays, thereby having the advantage of being able to have full sight (in V.R.) of the fracture region also from the sagittal standpoint, which is an advantage with respect to traditional fixator assisted reduction procedure.

Claims

1. Alignment System for instruments or fractures in Virtual Reality, characterised by the presence, between the end clamps of the instrument or of the fixator, of a six degrees of freedom measuring device connected to a computer, by a mechanism allowing adjustment of the relative clamp position acting in sequence on independent planes (regulating device), by an identification/calibration subsystem of the relative position between bone and measuring device (image calibrating device), by a device enabling to centre a given portion of the body (aiming device) and by a video image acquisition board and related specialised software.
2. Alignment System for instruments or fractures in Virtual Reality, as per claim 1, in which the measuring and regulating device are coupled on a single instrument, bearing six or more degrees of freedom, under manual motion control (Figure 10).
3. Alignment System for instruments or fractures in Virtual Reality, as per claim 1, in which the measuring and regulating device are coupled on a single instrument, bearing six or more degrees of freedom, under electronic motion control (Figure 11).
4. Alignment System for instruments or fractures in Virtual Reality, as per claim 1, in which the regulating device is incorporated in the fixator or on in the aiming device, while the measuring device bears the image calibrating device.
5. Aiming device for screws, nails, drills, etc. under fluoroscopy or in Virtual Reality characterised by two pairs of aiming elements each pair defining a plane on which the object to be aimed is to be placed, bearing at the interception between such planes, one or more holes whose axes are parallel to such intercept line, used to guide the instruments in reaching the region of clinical interest (Figure 5).
6. Regulating device able to allow aligning of the instruments working in sequence on different kinematic pairs, blocking the configuration one plane at the time, as represented in Figure 6, or in any other configuration bearing three telescopic pair and three hinges.
7. Regulating device able to allow aligning of the instruments working in sequence on different kinematic pairs, blocking the configuration one plane at the time, as repre-

sented in Figure 6 or in any other configuration bearing two telescopic pair and four hinges.

8. Regulating device able to allow aligning of the instruments working in sequence on different kinematic pairs, blocking the configuration one plane at the time, as represented in Figure 8.

9. Auxiliary mechanism to insert fiches with axis perpendicular to the diafisis, characterised by the presence of a telescopic element to be superimposed to the diafisis while perforating the cancellous bone (Figure 9).

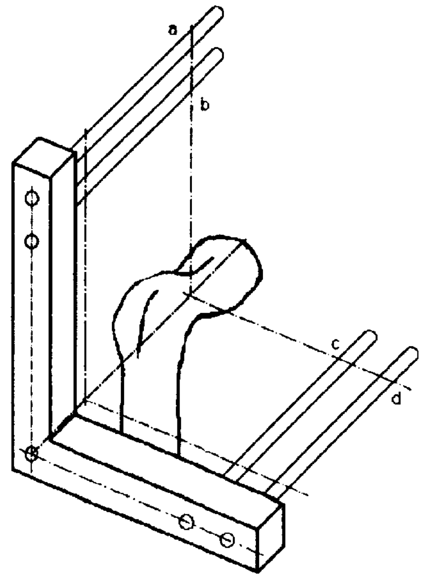

Figure 1 - Simple version of the aiming device

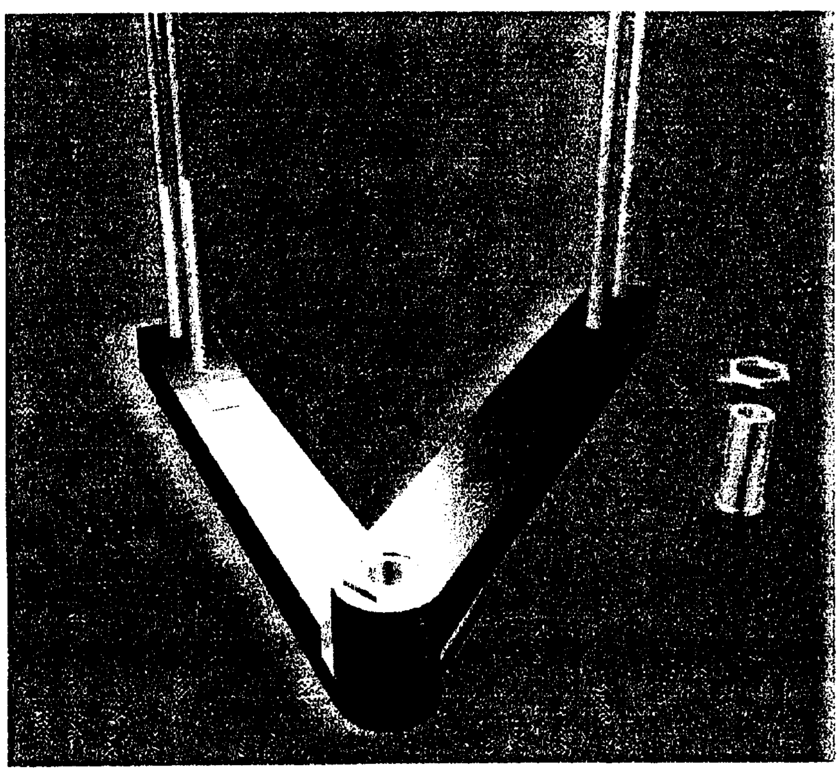

Figure 2 - More sofisticated version of previous device showing the variable angle, the interchangeable hinge and the telescopic arms

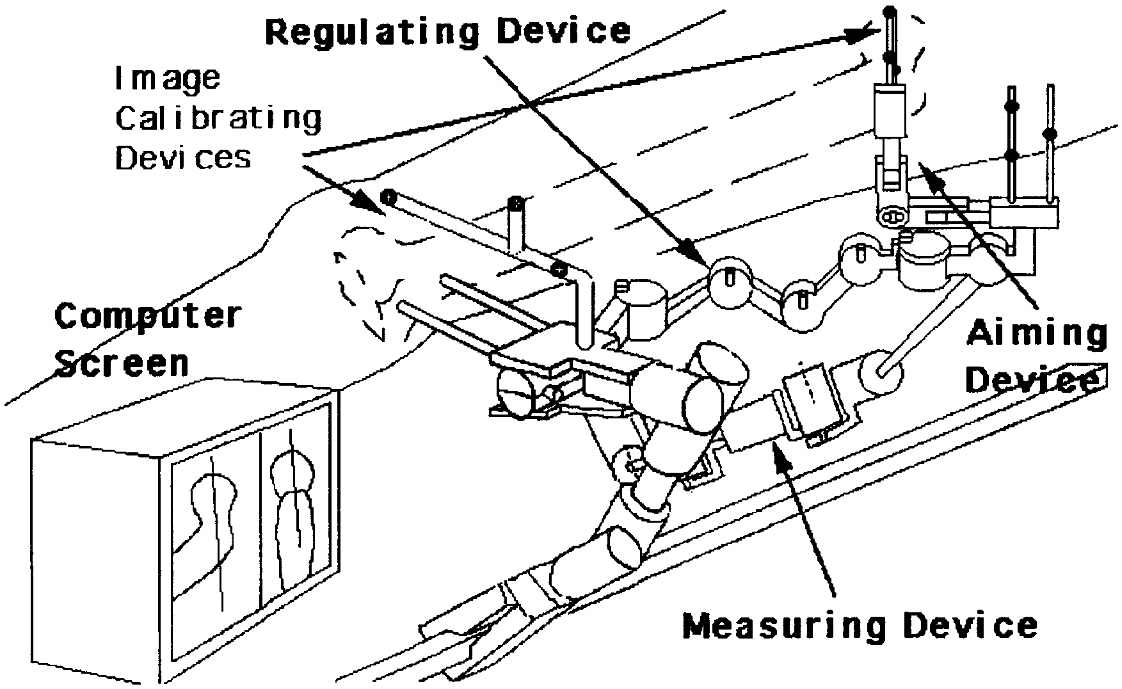

Figure 3 - Schematic Representation of guiding wires in a particular position acting under Virtual Reality

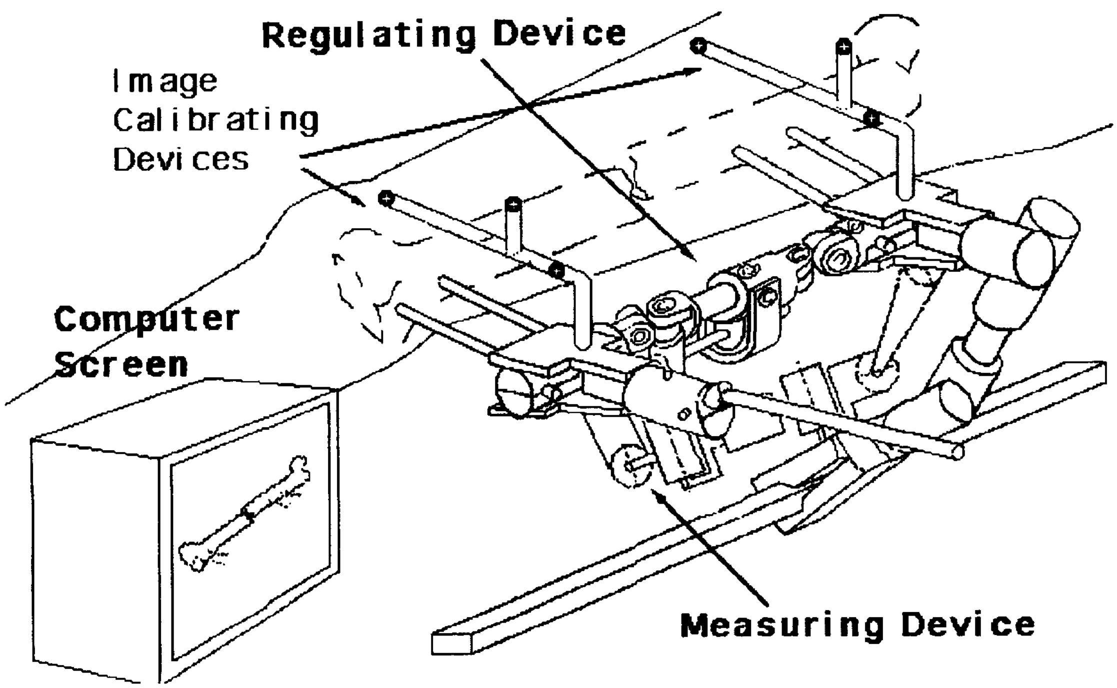

Figure 4 - Schematic Representation of fracture reduction in Virtual Reality

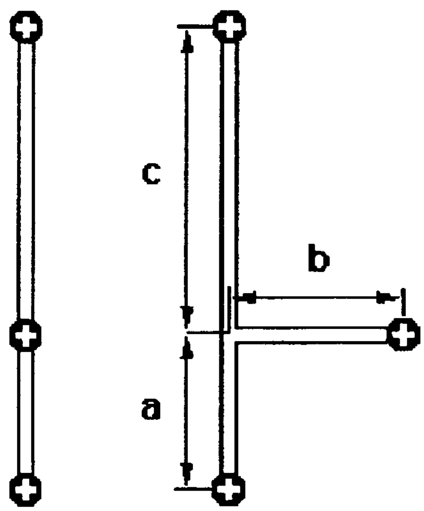

Figure 5 - Possible execution of an element of the image calibrating device

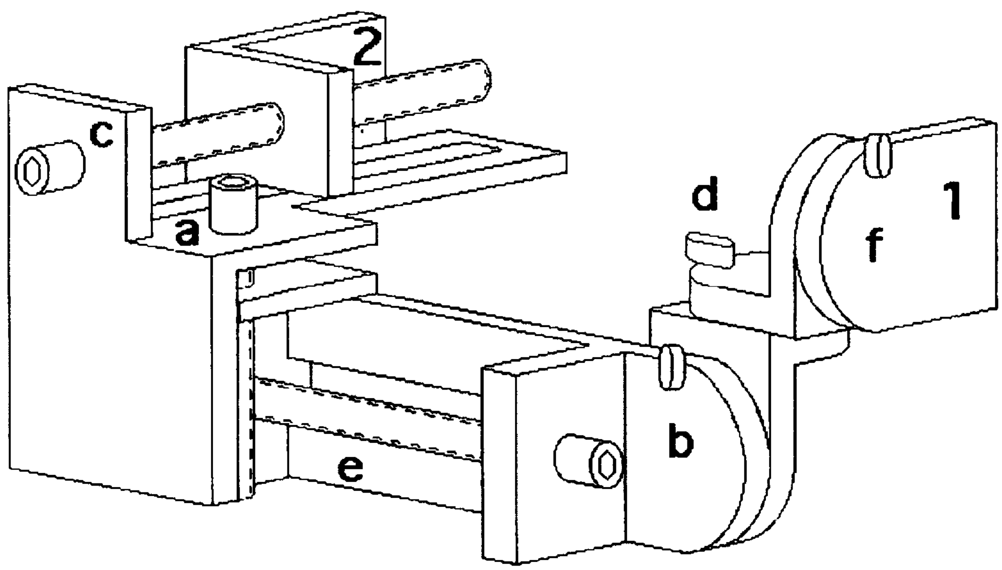

Figure 6 - Mechanical regulating device acting on independent planes, composed of three telescopic pairs and three hinges

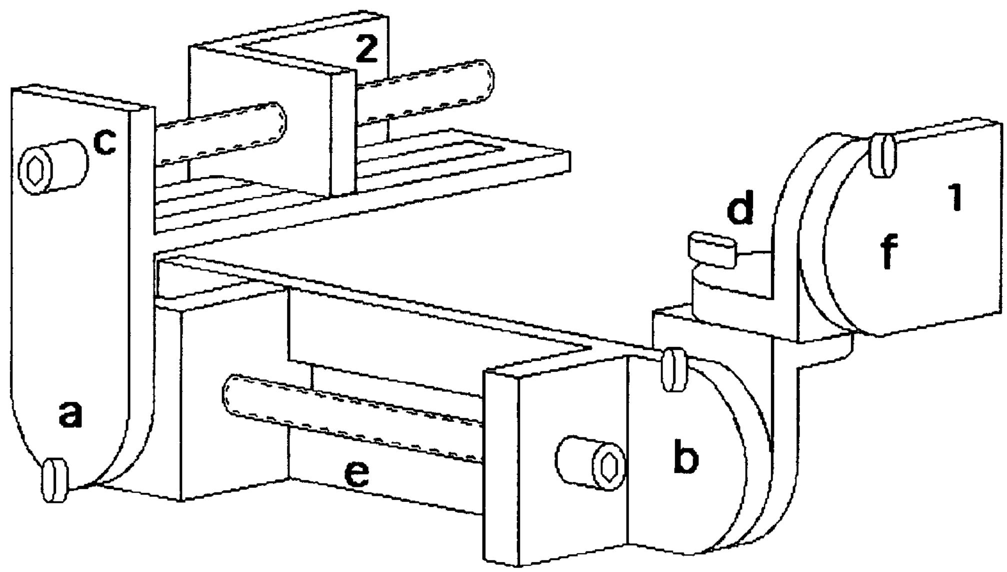

Figure 7 - Mechanical regulating device acting on independent planes, composed of two telescopic pairs and four hinges

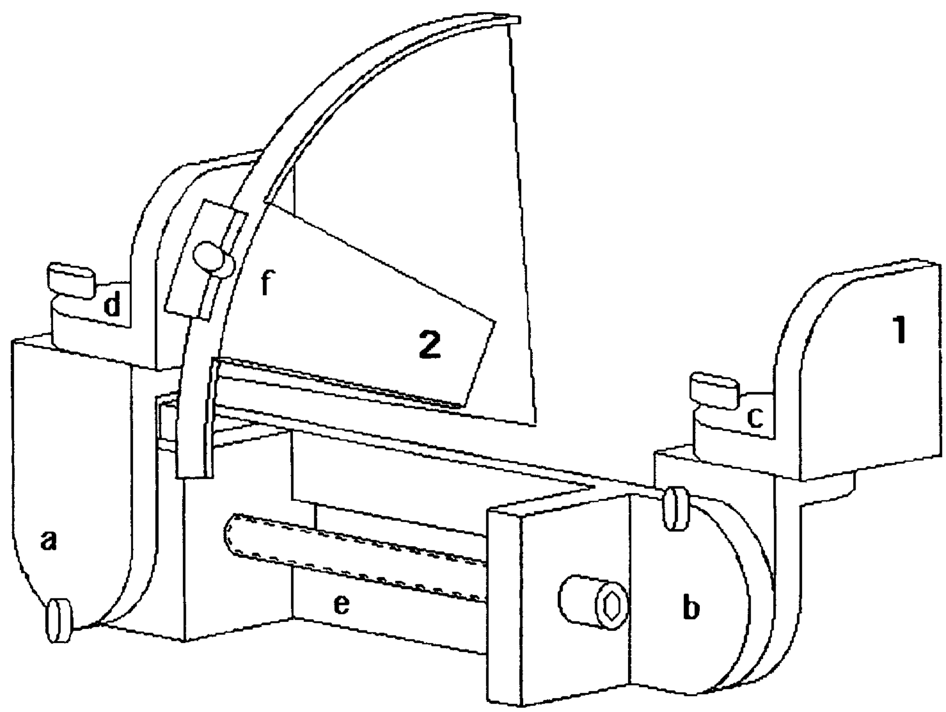

Figure 8 - Mechanical regulating device acting on independent planes, allowing pure rotation about the diafisis

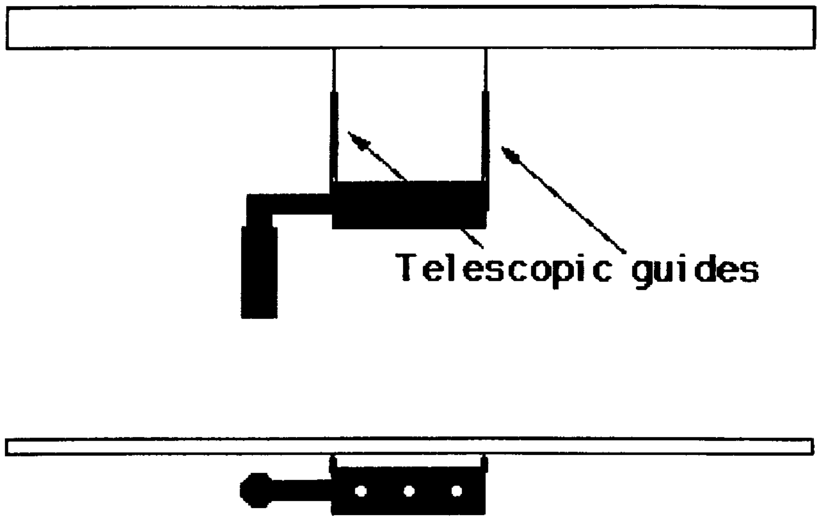

Figure 9 - Guiding instrument allowing to insert screws perendicularly to the diafisis

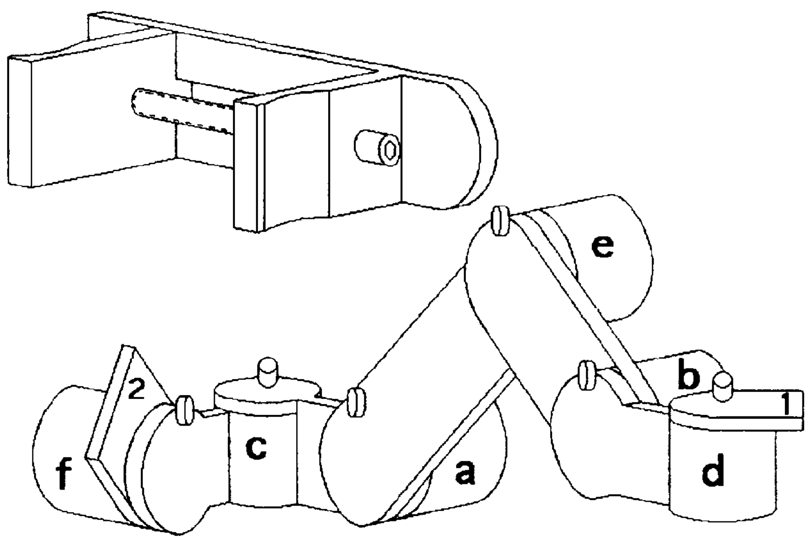

Figure 10 - Passive measuring/regulating electro-mechanical devicefor setting a fracture on independent planes (a-f are the angular encoders) and relative extensor

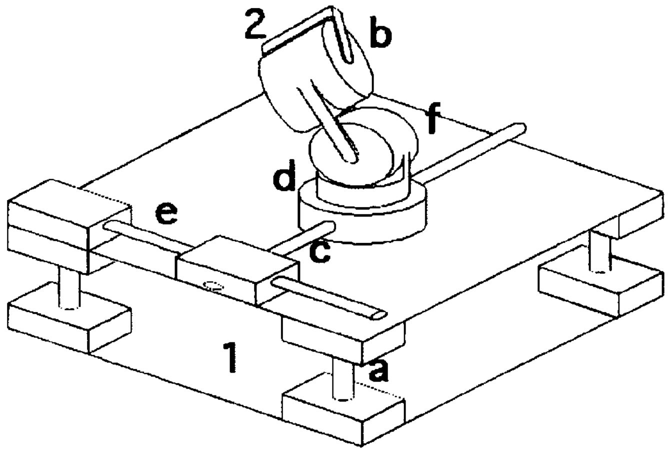

Figure 11 - Active measuring/regulating electro-mechanical devicefor setting a fracture on independent planes